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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/578,340 | 03/06/2007 | Larry Lapanashvili | 088790-000300US | 6589 |
| 20350 | 7590 | 08/05/2008 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP | | | LAVERT, NICOLE F | |
| TWO EMBARCADERO CENTER | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/578,340 | LAPANASHVILI, LARRY | |
| | Examiner | Art Unit | |
| | NICOLE F. LAVERT | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 April 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 15-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 April 2008 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/26/07</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 15-17, 20-21, 22-24 & 27-28** are rejected under 35 U.S.C. 102(b) as being anticipated by Lapanashvili (WO 2001/13390 A).

For **claim 15**, Lapanashvili et al. discloses, an electrotherapy apparatus for applying electrical stimulation to a muscle or group of muscles of a person or other mammal (pp 8, para 3), wherein said electrical stimulation comprises electrical pulses, said electrical stimulation having parameters comprising at least some of an amplitude, a pulse repetition frequency, a duration of each pulse or group of pulses [(pp 32, para 4) & (pp 33, para 1)] and a time offset relative to a predicted end of a T-wave of an electrocardiogram derived from said person or mammal (pp 19, para 2), said offset lying in a range from 5% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, before the predicted end of said T-wave up to 45% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, after the predicted end of the T-wave (pp 14, para 2), wherein the electrotherapy apparatus is adapted to vary at least one of said amplitude, said pulse repetition frequency, said duration and said

offset in accordance with a predetermined pattern stored in an associated microprocessor, or randomly in accordance with a random number generator, within pre-specified limits in the course of a treatment extending over many heart cycles, typically over more than 15 minutes, and from one heart cycle to the next or periodically or after a predetermined or randomly selected number of heart cycles [(pp 30, para 4) & (pp 31, para 1-2)].

In reference to **claim 16**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 15 (pp 8, para 3), wherein said amplitude variation amounts to a variation in peak voltage of said electrical stimulating pulses in a range from +10 V to -10 V from a nominal value selected in the range from typically 10 to 50 V (pp 27, para 1-2).

In reference to **claim 17**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 15 (pp 8, para 3), wherein said pulse repetition frequency lies in a range from 20 to 1000 Hz, and wherein said pulse repetition frequency can be varied within said range (pp 31, para 2).

In reference to **claim 20**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 15 (pp 8, para 3), wherein said offset can lie within said range from 5% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, before the predicted end of said T-wave up to 45% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, after the predicted end of the T-wave, and can be varied in this range (pp 14, para 2).

In reference to **claim 21**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 15 (pp 8, para 3), wherein a plurality of said parameters are simultaneously varied (pp 31, para 2).

For **claim 22**, Lapanashvili et al. discloses, a method for applying electrical stimulation to a muscle or group of muscles of a person or other mammal using electrotherapy apparatus (pp 8, para 3), wherein said electrical stimulation comprises electrical pulses, the electrical stimulation having parameters comprising at least some of an amplitude, a pulse repetition frequency, a duration of each pulse or group of pulses [(pp 32, para 4) & (pp 33, para 1)] and a time offset relative to a predicted end of a T-wave of an electrocardiogram derived from said person or mammal (pp 19, para 2), said offset lying in a range from 5% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, before the predicted end of said T-wave up to 45% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, after the predicted end of the T-wave (pp 14, para 2), wherein at least one of said amplitude, said pulse repetition frequency, said duration and said offset is varied in accordance with a predetermined pattern, or randomly, within pre-specified limits in the course of a treatment extending over many heart cycles (pp 31, para 2), typically over more than 15 minutes.

In reference to **claim 23**, Lapanashvili et al. discloses, a method in accordance with claim 22 (pp 8, para 3), wherein said amplitude variation is selected to amount to a variation in peak voltage of said electrical stimulating pulses in a range from +10 to -10 V from a nominal value selected in the range from typically 10 to 50 V (pp 27, para 1-2).

In reference to **claim 24**, Lapanashvili et al. discloses, a method in accordance with claim 22 (pp 8, para 3), wherein said pulse repetition frequency is selected to lie in a range from 20 to 1000 Hz, and wherein said pulse repetition frequency is varied within said range (pp 31, para 2).

In reference to **claim 27**, Lapanashvili et al. discloses, a method in accordance with claim 22 (pp 8, para 3), wherein said offset is selected to lie within said range from 5% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path length of a plurality of preceding heart cycles or of a representative R-R path length, before the predicted end of said T-wave up to 45% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path length of a plurality of preceding heart cycles, or of a representative R-R path length, after the predicted end of the T-wave, and is varied in this range or in a smaller range (pp 14, para 2)

In reference to **claim 28**, Lapanashvili et al. discloses, a method in accordance with claim 22 (pp 8, para 3), wherein a plurality of said parameters are simultaneously varied (pp 31, para 2).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 18-19 & 25-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lapanashvili et al. (WO 2001/13990 A) in view. Minogue et al. (US 20020058972 A1).

Lapanashvili et al. shows all the features of the instantly claimed invention as discussed above.

Lapanashvili et al. fails to disclose intervals of pulse duration ranges within .1 ms to 600ms and .1 ms to 60ms.

Minogue et al. teaches the duration of pulses of each pulsed signal varied between 50 microseconds and 1000 microseconds or between 5 milliseconds and 1000 milliseconds [0146].

It would have been obvious to one of ordinary skill in the electrotherapy art to have modified Lapanashvili et al. with the use of durations of pulses of each pulsed signal varied between 50 microseconds and 1000 microseconds or between 5 milliseconds and 1000 milliseconds, as taught by Minogue et al., in order to provide predictable results pertaining to manually varying the magnitude of the pulses so as to provide efficient electrotherapy to the heart [Minogue, 0147].

In reference to **claim 18**, Lapanashvili et al. in view of Minogue et al. teaches, an electrotherapy apparatus in accordance with claim 15 (Lapanashvili, pp 8, para 3), wherein said pulse duration lies in the range from 0.1 ms to 600 ms and can be varied in this range [Minogue, 0146].

In reference to **claim 19**, Lapanashvili et al. in view of Minogue et al. teaches, an electrotherapy apparatus in accordance with claim 15 (Lapanashvili, pp 8, para 3), wherein an interval between successive pulses lies in a range from 0.1 ms to 50 ms and can be varied in this range [Minogue, 0146].

In reference to **claim 25**, Lapanashvili et al. in view of Minogue et al. teaches, a method in accordance with claim 22 (Lapanashvili, pp 8, para 3), wherein said pulse duration is selected

to lie in the range from 0.1 ms to 600 ms or smaller and is varied within this range or in a smaller range [Minogue, 0146].

In reference to **claim 26**, Lapanashvili et al. in view of Minogue et al. teaches, a method in accordance with claim 22 (Lapanashvili, pp 8, para 3), wherein an interval between successive pulses is selected to lie in a range from 0.1 ms to 50 ms and is varied in this range or in a smaller range [Minogue, 0146].

Response to Arguments

1. Applicant's arguments filed 18 April 2008 have been fully considered but they are not persuasive. The Examiner has maintained the original rejection sent out on 15 November 2007. The Applicant argues that the Lapanashvili reference, WO 2001/13990, is not an effective prior art reference against the present application because the filing date of Lapanashvili is August 14, 2000, which does not beat the priority date of August 20, 1999 set forth by the application 09/378,181 (see ADS). The Examiner argues the priority date set forth by the Applicant is not properly appointed and further points out that the disclosure of 09/378,181 does not fully support the claims of the current invention and therefore the present application is not given the priority date of August 20, 1999.

2. Applicant's arguments, filed 18 April 2008, with respect to the objections of the drawings and specification have been fully considered and are persuasive. Therefore the above objections of the drawings and specification have been withdrawn.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (Alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762